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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,689	08/02/2001	Mark T. Anderson	56240US003	6481

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EXAMINER
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LEVY, NEIL S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

09 920689 ANDERSON et al  
NBL/ey 1616 7

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 10/24/02
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-108 is/are pending in the application.
- Of the above claim(s) 42-84 & 93-108 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-41485-92 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1-108 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 2, 3
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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Applicant's election with traverse of Group I in Paper No. 5 is acknowledged. The traversal is on the ground(s) that Group ~~I-VI~~<sup>I-VI</sup> fall within the same class, and examination of claims of each of Group ~~I-VI~~<sup>I-VI</sup> would have to be as rigorous as that of only Group I. This is not found persuasive because for the reasons applicant has identified; as rigorous an examination of Group II, III, IV, V, VI and VII would be required as is required for Group I in essence, 6 times more work, an excessive burden to perform quality examination and determination of patentability of each of the separately patentable groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 42-84, 93-108 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-41, 85-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear if an organic compound, complex or article (an agent) or if an agent that directs organic structure, is being claimed (claim 1). It is unclear in either case what is intended by "Structure directing". It is unclear what is intended by "controllably releasing", and by what means the particle would be capable of utilizing and how the

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particle, in what manner; would control release. It is unclear what is intended by "associated" as to the metes and bounds of the claim limitation. The language "greater than about" is indefinite which is it - no greater, or about?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-6, 9, 10, 12, 13, 18-20, 22-24, 26-31, 35, 39, 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Ducheyne et al 559/453.

Instant claim 1, to a particle of inorganic matrix with in which is a composition having an, active agent is met by the particle~~the~~ controlled release granule, disc of silica within the matrix of which are growth factors, Drugs, antibiotics (col. 9, line 19 – col. 10, line 2), all (the plurality) immersed in the vehicle of SPS – the instant claim 27, 85 composition and claim 30, water vehicle. As to the organic structure – directing limitation, the structure, porous, of the particle, is controlled by protons or water (col. 9, lines 9-18) or TMOS (col. 13, lines 20-26), a surfactant. Template compositions, inclusive of CA salts, may be incorporated (col. 13, lines 54-63). Example 1 shows incorporation of TMOS composition with an associated antimicrobial agent, vancomycin, hydrophilic. Hydrophobic actives are also shown (col. 10, lines 50-53). Curing agents are met by the acid (col. 14, lines 16-20). The curing agent, acid, in a water-directing agent meets the instant claim 12 to a disclosed active. Pore size is shown at Fig. 1; - 10 microns and smaller; 1.8 nm (col. 17, lines 6-15) in both parallel and interconnected

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channels. Metal oxides are Ca O (Table II), and other oxides col. 9, lines 52-53).

Polymerizable monomer are used/ TMO, methanol, Ca, P.

Claims 1, 2, 4-6, 9, 10, 12-17, 20, 24, 25, 27-31, 34, 35, 39, 85 are rejected under 35 U.S.C. 102(b) as being anticipated by Constantz - 6005162.

Here, too, (col. 8, top) porous particles are obtained, with the instant actives (col. 8, paragraphs 2,3) and structure directing and controlling releasing additives (col. 7, top). Particle size is as low as sub micron size (col. 5, lines 45-55 col. 4, lines 9-11). Templates of calcium salts, sugars and Lubricants are envisioned (col. 7, top). Monomers or Surfactants, polyols, and metal oxides, alumina (col. 5, lines 14, 59-67) and adhesives (bone cements) as vehicle (col. 7, lines 50-58) are taught.

Claims 1, 2, 4-6, 9, 10, 13-17, 20, 21, 24, 25, 27, 29-36, 85 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al 6027742.

Monomers (Ca P) with sub micron and nano particles in a matrix, with CaP vehicle (col. 9, 2<sup>nd</sup> paragraph) and thermoset or thermoplastic polymers (paragraph 3) are taught. The particles are porous (col. 11, lines 47-56) containing bioactives – cells, or other drugs (col. 14, bottom). Structure directors include mg, casein, polyacrylate (col. 14, lines 49-61). Hardening, or curing by promoters (col. 5, bottom, col. 6. “promoter” col. 16, bottom). Adhesives – Example 10, bone glue – (col. 12, bottom) is shown, as is added alumina (col. 17, top). Latex particles at col. 9, lines 49-63.

Claims 1, 3, 5, 10, 12, 13, 18-20, 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Beck-5057296.

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See col. 5, 6 and Fig. 1; the instant particles of inorganic, with 13-200 Å pores. Active agents aluminum are added in processing (col. 9, lines 45-49). Directing agents are organics, (at col. 14, line 50 – line 8, col. 15). Particle size is less than 100 micron (col. 15, lines 10-14). Silica constitutes the inorganic matrix; Example 1.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9, 10, 12, 13, 18-20, 22-24, 26-35, 37-41, 85-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ducheyne et al 5591453 in view of Cataldo et al 5856211.

As shown above, Ducheyne provides the essence of the instant invention, but not the x ray diffraction, pheromones, pore size. Ducheyne (col. 1, lines 11-14) is directed to bio-active glass controlled delivery. Pore size is shown as determinable by artisan (col. 14, lines 28-29); so small molecules can be released from smaller pore size, thus of the instant claims 18, 19. X-ray diffraction shown is (fig. 2) of the silica based particle; however, bone type matrices, with the consequent X ray pattern of instant claim 3 are evident, when the composition is a bone replacement with added Ca-P (col. 9, lines 33-41, col. 10, lines 13-16). Although pheromones are absent, Hormones are used, insulin and other small molecules – drugs.

Cataldo also does controlled delivery, using inorganic matrices within vehicles of polymers (summary-col.2). Polymers are at col. 3, with CaP (apatite) or carbon black mixed with active, which include pesticides, and pheromones (col. 4, lines 13-16).

Thus, it would be obvious to one of ordinary skill in the art desiring to utilize ecologically safe compositions to use controlled delivery, as is known in the art, with specific ingredients shown by Cataldo.

It has not clearly been established by objective showing of unobvious and/or unexpected results, that the administration of the particular form of active, carrier, or the particular form of structure, provides any greater level of prior art expectations as claimed. Further, no criticality as to the active agents has been shown by applicant; neither has their concentration, they would be within the purview of one to use as drugs (Ducheyne) or pheromones (Cataldo) depending upon desired effects.

The selection of each ingredient and form thereof is a result effective parameter chosen to obtain the desired effect. It would be obvious to vary the nature of each ingredient to optimize the effects desired, and the use ingredients for the functionality for which they are known to be used is not basis for patentability.

This application contains claims directed to the following patentably distinct species of the claimed invention ultimate species of active agent, as included in claim 8 and 11, for example.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-41, 85-92 is generic.

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This application contains claims directed to the following patentably distinct species of the invention: ultimate species of inorganic matrix, as shown at claim 25, for example.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-25, 27-40, 85-87, 89-92 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: species of directing agent.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-19, 22-34, 37-41 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: This application contains claims directed to the following patentably distinct species of the claimed invention: species of vehicle.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 27-30, 35-38 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.



Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (703)308-2412. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



NEIL S. LEVY  
PRIMARY EXAMINER